Resolution

Efficiency in Standards Development and Revision

USP will proactively evaluate and enhance the process for developing and updating standards to maintain and continuously optimize their impact. In doing so, USP will consider the perspectives and implications of process modifications from FDA, industry, practitioners, and other stakeholders. A focus of this work will be to explore new approaches for the efficient sharing of information that is critical to standards development, along with the information needed for the evaluation of fit-for-purpose analytical methods and specifications, and the integration of appropriate scientific and manufacturing advances into USP standards.

Year 3 Update

USP standards support global medicines supply chain resilience, helping to increase access to safe, quality medicines people can trust. USP continued to engage with FDA, industry, healthcare practitioners, and other stakeholders to maintain a modernized *U.S. Pharmacopeia-National Formulary* (*USP–NF*) compendia through collaboration and implementation of efficient processes for continually developing and revising quality standards. This included working with FDA and industry on new approaches for sharing the information needed for efficient standards setting, advancing access to quality medicines, and helping protect patients.

Key areas of progress over the past fiscal year include:

Adapt-Transform-Progress – USP continued to operationalize solutions through its Adapt-Transform-Progress (ATP) initiative, advancing the standards development process for greater efficiency and effectiveness. For example, USP marked significant progress in its implementation of a Business Process Management (BPM) application that facilitates automation of select processes within standards development, resulting in increased consistency and control. USP launched the first release of the BPM platform for documentary standards in February 2023 and continued to develop enhancements – including for its existing BPM platform for reference standards – to improve functionality of the system. By leveraging the BPM platform for documentary standards, USP operationalized various case-based methods to bolster its strategic approach to standards development.

Standards Engagement Model – This cycle, USP is focused on advancing a more iterative and agile approach to standards development. During the fiscal year, USP developed an agile framework for engagement throughout and before the

standards lifecycle begins, delivering on its commitment to efficient and effective standards development. Collaborating with stakeholders, USP focused on early and appropriate stakeholder involvement, early insights, and input for "fit-for-purpose" standards, all while ensuring transparency and accessibility. This approach included alignment with USP's principles for diversity, equity, inclusion, and belonging (DEIB), in partnership with the USP Equity Office. USP continues to further integrate DEIB principles across the Council of Experts (CoE) through adoption of a DEIB-centric approach for CoE candidate selection and implementation of USP's health equity principles. The following are key points of progress:

- Review of lessons learned and best practices to enhance USP stakeholder engagement approaches, and rollout of a stakeholder engagement model identifying four phases – early, pre-compendial, compendial, and post-publication – to drive a more consistent approach to stakeholder engagement.
- Revamping how Expert Committee chairs are identified, to include a more rigorous and transparent process and diverse pool of candidates.
- Expanding the Call for Candidates to be more inclusive to promote and support diversity, and broadening the Scientific Expert Fellowship Program with incremental increases in the cohort of fellows each fiscal year.
- Development and execution of a robust Expert Volunteer Experience strategy that will strengthen the experience for volunteers, growing their commitment to USP and attracting the next generation of volunteers.
- Providing support for a participant in the National Urban Fellows program throughout the year.

Science Quality Framework – The Science Quality Framework (SQF) establishes a consistent set of focus areas and principles that help guide our science priorities and the work of our expert bodies. Related accomplishments during the fiscal year included:

- Advancements in the detection of impurities, including new *USP* General Chapter <477> *User-Determined Reporting Thresholds*, which provides an approach for determining the appropriate numeric reporting threshold value for organic impurities test procedures in monographs within the *USP-NF*. In addition, USP has prioritized its focus on detection of nitrosamines and how best to mitigate the risk of these impurities being above acceptable levels. This includes a physical analytical impurities (PAIs) catalog for nitrosamines as well as other PAIs.
- Increased prioritization of complex generics, including documentary standards and physical materials needed by manufacturers and vendors for products with complex active pharmaceutical ingredients (APIs), formulations, routes of delivery, dosage forms, and drug-device combination products. To date, USP has identified more than 100 candidate materials, including extractables and leachables, dissolution materials, reagents, non-U.S. APIs, and injectable physical materials.
- Greater attention to supply chain resiliency with the development of *USP* General Chapter <1083> *Supplier Qualification* to help assist in qualifying suppliers of raw materials, ingredients, and services for medicines, foods, and dietary supplement ingredients. This can help safeguard the integrity of supply chains globally.
- Addressing advanced manufacturing techniques – including development of a technical guide on control strategy as

well as three proposed new standards for the physical properties of material used in pharmaceutical continuous manufacturing (PCM) – to help reduce potential industry barriers to widespread PCM adoption.

- Preparing for anticipated demand for the digital evolution of standards through a pilot initiated for USP's nuclear magnetic resonance (NMR) analysis software platform USP-ID, which allows NMR spectral data to function as digital references by combining high-quality chemical reference databases with smart algorithms that automate identity, strength, and purity analysis of molecules in complex mixtures. (See Digital Transformation of Standards Resolution update.) In addition, USP revised General Chapters <761> *Nuclear Magnetic Resonance Spectroscopy* and <1761> *Applications of Nuclear Magnetic Resonance Spectroscopy* in response to comments received from stakeholders, facilitating the use of NMR as an analytical technique for demonstrating quality. USP also initiated General Chapter <1762> on solid-state NMR to incorporate modern technologies and contemporary practices of NMR spectroscopy, and published a *Stimuli* article on "Consistent Terminology for Advancement of NMR Spectroscopy."

Government Liaison Program – USP collaborated with FDA on the Government Liaison Program across several key areas during the year, including:

- Enhancing stakeholder involvement in standards-setting activities by increasing the number of FDA government liaison appointments within USP's expert bodies to 316, thus further integrating FDA's perspective while ensuring better alignment with stakeholder needs and expectations.
- Drafting a USP-FDA memorandum of understanding (MOU) aimed at streamlining information exchange, fostering efficient quality standards development, and bolstering collaborative efforts, demonstrating USP's commitment to facilitating collaboration and promoting quality standards.

Information Sharing – USP, in collaboration with the FDA and industry, continued to advance standards development by enhancing information exchange and revising compendial processes. This progress, which included incorporation of key language in FDA communications to industry, aimed to inform industry on how to collaborate with USP to develop standards.

Planned for Remainder of the Cycle

- USP will continue to advance initiatives to develop standards and other informational resources that respond to key trends in science and technology, and will leverage opportunities to assist stakeholders in enhancing the quality of drug products, excipients, and foods across the global supply chain.
- USP will complete the second major BPM release focused on documentary standards, while simultaneously advancing BPM development to support both documentary and reference standards, further demonstrating our commitment to enhance case-based standards development.
- The draft FDA-USP MOU will be finalized and submitted for agency and USP approval.
- USP will implement a refined, real-time reporting mechanism enabling FDA liaisons, USP staff, and volunteers to swiftly highlight operational successes

and challenges, which will also facilitate prompt identification of trends and issues across expert bodies by USP.

- USP will aim to expand its engagement across FDA by coordinating training in agency centers that are less familiar with USP-NF.
- USP will advance its collaborative efforts with the FDA and the Association for Accessible Medicines, focusing on a joint webinar on standards development targeted for launch in autumn 2024 (Fiscal Year 2025).
- USP will continue to streamline efforts to leverage the four-phase stakeholder engagement model by improving the ability to receive feedback across the different phases, increasing ease of access to information as well as ways to deliver scientific content.
- USP will continue to integrate USP's health equity principles, and principles for diversity, equity, inclusion, and belonging, into the USP Expert Volunteer experience and across the CoE to broaden its composition.

Contact

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